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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,383	01/22/2002	Indra Sandal	056859-0137	6958

22428 7590 09/03/2004

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/051,383	Applicant(s) SANDAL ET AL.	
	Examiner Georgia L. Helmer	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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***Status of the Claims***

1. The Office acknowledges receipt of Applicant's Response; dated 14 June 2004. Applicant has cancelled claims 1-25 and added new claims 26-54. Claims 26-54 are pending and are examined in the instant action.
2. This action is made FINAL necessitated by Applicant's amendment.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup>***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is an incomplete method claim because the last step of the method does not produce the desired product, namely a transgenic tea plant.

In Claim 33, "wherein the explant is in a chamber receptive to particle bombardment" is unclear because qualities of "receptive" are not apparent. Suggested language is replacing "receptive" with "appropriate". Furthermore, the method of 26 includes several sequential steps; and it is unclear at what step(s) the limitation of claim 33 applies.

Dependent claims of claim 33 are also rejected, for the same reasons.

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In claim 38, at what step does of the sequential steps does the “vacuum” apply?

In claim 48, line 2, “comprises” should be “comprising”.

In claim 53, “after the explants have been bombarded once”, where does this limitation apply? Suggested language includes “and before step...”.

***Claim Rejections - 35 USC § 112.1***

7. Claims 26-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 8-10 of the last office action for claims 1-25.

Applicant traverses saying primarily that contrary to Examiner’s allegation, the present specification relates four experimental examples (Response of 14 June 2004, p. 6). Attention is drawn to panels (d) to (r ) of Figure 1 of the instant application, “which are photographs of tea leaf explants that have been biolistically transformed according to the methods and conditions detailed in experimental examples 1, 2, 3, and 4”. Applicant further says that “Figure 1 shows the results of these actual experiments.”

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Applicant's traversal is unpersuasive. Figure 1 of the instant case is described (specification p. 13, under "Brief description of the accompanying drawing" ) as "Figure 1 a.,b.,c., represents: Leaf explant of tea plants" and Figure "1 d to r represents: different transformed leaf explant showing gus expression". The Examiner interprets this to say that Figures 1 a-c are controls and Figures d-r are treated explants. However, Examiner's observation of Figure 1, panels a-c, shows leaf explants having blue spots and speckles, while observation of Figure 1, panels d-r, shows leaf explants (15 panels in all), some of which (4 or 5) show blue spots or sectors. In the absence of other information, this Gus gene expression evidence for transformed tea tissue by the claimed method is indecisive or negative, since the level of gus expression in the controls is equivalent to that in the transformants.

Applicant traverses saying primarily that "Applicant tested different concentrations of osmotic agents (example 2, page 14); different cultivars (example 3, page 14); and different explants, such as somatic embryos, zygotic embryos, and embryogenic calli (example 4, page 14)". Applicant's traversal is unpersuasive. Examples 2, 3, and 4 give no information of the result of these testings. Furthermore, the sole piece of evidence, Figure 1, is limited to leaf explants. Even Figure 1 fails to demonstrated that whole transgenic tea plants were regenerated from the allegedly transformed explants, as claimed.

Applicant is invited to supply clarification and other information, preferably as a Rule 1.132 Declaration, about Applicant's results with the claimed invention.

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This declaration should demonstrate that only those techniques and starting materials set forth in the specification were relied upon.

***Remarks***

8. Claims 26-54 are free of the prior art of record, given the failure of the prior art to teach or reasonably suggest the production of transgenic tea by a biolistics process comprising the limitations of these claims.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

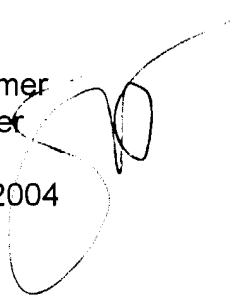
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
September 2, 2004



DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180- 1638

